

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Assaf Govari Confirmation No.: 6087
Appln. No. : 10/029,595
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Title : IMPLANTABLE AND INSERTABLE TAGS

Art Unit : 3737
Examiner : Roy Baisakhi

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April 18, 2007

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RESPONSE

Dear Sir:

In response to the Office Action of December 12, 2006, Applicant responds as follows:

Amendments to the Claims are reflected in the listing of claims which begins on Page 2 of this paper.

Remarks begin on Page 12 of this paper.

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1. (Previously Presented) Apparatus for determining the position of an object within a body of a subject, comprising:
at least one acoustic wave generator, adapted to direct a first acoustic wave toward the body at a first frequency;
an acoustic tag adapted to be fixed to the object, the tag being wireless and comprising a shell defining a cavity therein and a medium contained within the shell, such that responsive to incidence thereon of the first acoustic wave, the tag emits a second acoustic wave at a second frequency, different from the first frequency;
one or more detectors, adapted to detect the second acoustic wave and to generate signals responsive thereto; and
a signal processor, coupled to process the signals so as to determine six-dimensional position and orientation coordinates of the object in the body.

Claim 2. (Canceled)

Claim 3. (Original) Apparatus according to claim 1, wherein the tag has an axis and is constructed so that responsive to incidence thereon of the first acoustic wave, the tag emits the second acoustic wave at the second frequency with a first pattern of intensity variation relative to the axis, and a third acoustic wave at a third frequency, different from the first and second frequencies, with a second pattern of intensity variation relative to the axis, and wherein responsive to detection of the second and third acoustic waves by the one or more detectors, the signal

processor is adapted to determine an angular orientation of the object responsive to a difference between the first and second patterns.

Claim 4. (Previously Presented)

Apparatus for determining the position of an object within a body of a subject, comprising:

at least one acoustic wave generator, adapted to direct acoustic waves toward the body over a range of frequencies, including at least first and second frequencies;

an acoustic tag adapted to be fixed to the object, the tag being wireless and constructed so as to reflect the acoustic waves at the first frequency with a first spatial pattern of intensity variation, and to reflect the acoustic waves at the second frequency with a second spatial pattern of intensity variation;

one or more detectors, adapted to detect the reflected acoustic waves and to generate signals responsive thereto; and

a signal processor, coupled to process the signals so as to determine six-dimensional position and orientation coordinates of the object in the body responsive to a difference between the first and second spatial patterns.

Claim 5. (Canceled)

Claim 6. (Original)

Apparatus according to claim 4, wherein the tag has an axis, and wherein the tag is constructed so that in the first spatial pattern, the acoustic waves are reflected predominantly in a first direction relative to the axis, while in the second spatial pattern, the acoustic waves are reflected predominantly in a second direction relative to the axis, different from the first direction.

Claim 7. (Canceled)

- Claim 8. (Previously Presented) Apparatus for determining the position of an object within a body of a subject, comprising:
at least one acoustic wave generator, adapted to direct acoustic waves toward the body;
a transducer adapted to be fixed to the object, the transducer being wireless and constructed to emit electromagnetic radiation responsive to the acoustic waves with a response that varies depending on an orientation angle of the transducer relative to the at least one acoustic wave generator;
one or more detectors, adapted to detect the electromagnetic radiation emitted by the transducer and to generate signals responsive thereto; and
a signal processor, coupled to process the signals so as to determine six-dimensional position and orientation coordinates of the object in the body.
- Claim 9. (Original) Apparatus according to claim 8, wherein the transducer comprises a piezoelectric crystal, which is polarized so as to respond anisotropically to the acoustic waves.
- Claim 10. (Original) Apparatus according to claim 9, wherein the piezoelectric crystal has multiple opposing faces, and wherein the transducer further comprises a plurality of resonant circuit elements having different, respective resonant frequencies, the circuit elements being coupled between respective pairs of the faces of the crystal so as to emit the electromagnetic radiation at the different resonant frequencies with respective amplitudes that vary responsive to the orientation angle of the transducer.

- Claim 11. (Original) Apparatus according to claim 10, wherein the circuit elements comprise coils having different, respective values of inductance.
- Claim 12. (Canceled)
- Claim 13. (Original) Apparatus according to claim 8, wherein the transducer comprises a magnetostrictive element, which is shaped so as to respond anisotropically to the acoustic waves.
- Claim 14. (Original) Apparatus according to claim 13, wherein the magnetostrictive element is shaped to as to focus the electromagnetic radiation that it emits.
- Claim 15. (Canceled)
- Claim 16. (Previously Presented) Apparatus for determining the position of an object within a body of a subject, comprising:
at least one field generator, adapted to generate an electromagnetic field within the body;
a transducer adapted to be fixed to the object, the transducer being wireless and constructed to emit acoustic waves responsive to the electromagnetic field;
one or more acoustic detectors, adapted to detect the acoustic waves emitted by the transducer and to generate signals responsive thereto; and
a signal processor, coupled to process the signals so as to determine six-dimensional position and orientation coordinates of the object in the body.
- Claim 17. (Original) Apparatus according to claim 16, wherein the transducer comprises a piezoelectric crystal, which is polarized so as to respond anisotropically to the electromagnetic field.
- Claim 18. (Original) Apparatus according to claim 17, wherein the piezoelectric crystal has multiple opposing faces, and

wherein the transducer further comprises a plurality of resonant circuit elements having different, respective resonant frequencies, the circuit elements being coupled between respective pairs of the faces of the crystal so as to cause the crystal to emit the acoustic waves at the different resonant frequencies with respective amplitudes that vary responsive to the orientation angle of the transducer.

Claim 19. (Original) Apparatus according to claim 18, wherein the circuit elements comprise coils having different, respective values of inductance.

Claim 20. (Original) Apparatus according to claim 16, wherein the transducer comprises a magnetoacoustic transducer.

Claim 21. (Original) Apparatus according to claim 20, wherein the transducer comprises a magnetostrictive material.

Claim 22. (Original) Apparatus according to claim 20, wherein the magnetoacoustic transducer is shaped so as to respond anisotropically to the electromagnetic field, so that the acoustic waves emitted thereby vary as a function of an orientation angle of the transducer relative to the at least one field generator, and wherein the signal processor is adapted to determine the orientation angle of the object responsive to the signals.

Claim 23. (Original) Apparatus according to claim 22, wherein the magnetoacoustic element is shaped to as to focus the electromagnetic radiation that it emits.

Claim 24. (Canceled)

Claim 25. (Previously Presented) A method for determining the position of an object within a body of a subject, comprising:

fixing an acoustic tag to the object, the tag being wireless and comprising a shell defining a cavity therein and a medium contained within the shell, such that responsive to incidence thereon of a first acoustic wave at a first frequency, the tag emits a second acoustic wave at a second frequency, different from the first frequency;

inserting the object into the body of the subject;

directing the first acoustic wave toward the body at the first frequency, causing the tag to emit the second acoustic wave at the second frequency;

detecting the second acoustic wave and generating signals responsive thereto; and

processing the signals so as to determine six-dimensional position and orientation coordinates of the object in the body.

Claim 26. (Canceled)

Claim 27. (Original)

A method according to claim 25, wherein the tag has an axis and is constructed so that responsive to incidence thereon of the first acoustic wave, the tag emits the second acoustic wave at the second frequency with a first pattern of intensity variation relative to the axis, and a third acoustic wave at a third frequency, different from the first and second frequencies, with a second pattern of intensity variation relative to the axis, and comprising detecting the third acoustic wave and generating the signals responsive thereto, wherein processing the signals comprises determining an angular orientation of the object responsive to a difference between the first and second patterns.

Claim 28. (Previously Presented) A method for determining the position of an object within a body of a subject, comprising:
fixing an acoustic tag to the object, the tag being wireless and constructed so as to reflect acoustic waves at a first frequency with a first spatial pattern of intensity variation, and to reflect acoustic waves at a second frequency with a second spatial pattern of intensity variation;
inserting the object into the body of the subject;
directing the acoustic waves toward the body over a range of frequencies, including at least the first and second frequencies;
detecting the reflected acoustic waves and generating signals responsive thereto; and
processing the signals so as to determine six-dimensional position and orientation coordinates of the object in the body responsive to a difference between the first and second spatial patterns.

Claim 29. (Canceled)

Claim 30. (Original) A method according to claim 28, wherein the tag has an axis, and wherein the tag is constructed so that in the first spatial pattern, the acoustic waves are reflected predominantly in a first direction relative to the axis, while in the second spatial pattern, the acoustic waves are reflected predominantly in a second direction relative to the axis, different from the first direction.

Claim 31. (Canceled)

Claim 32. (Previously Presented) A method for determining the position of an object within a body of a subject, comprising:
fixing a transducer to the object, the transducer being wireless and configured to emit electromagnetic

radiation responsive to acoustic waves incident thereon with a response that varies depending on an orientation angle of the transducer relative to a source of the acoustic waves;

inserting the object into the body of the subject;

directing the acoustic waves toward the body;

detecting the electromagnetic radiation emitted by the transducer responsive to the acoustic waves, and generating signals responsive thereto; and

processing the signals so as to determine six-dimensional position and orientation coordinates of the object in the body.

Claim 33. (Original)

A method according to claim 32, wherein the transducer comprises a piezoelectric crystal, which is polarized so as to respond anisotropically to the acoustic waves.

Claim 34. (Original)

A method according to claim 33, wherein the piezoelectric crystal has multiple opposing faces, and wherein the transducer further comprises a plurality of resonant circuit elements having different, respective resonant frequencies, the circuit elements being coupled between respective pairs of the faces of the crystal so as to emit the electromagnetic radiation at the different resonant frequencies with respective amplitudes that vary responsive to the orientation angle of the transducer.

Claim 35. (Original)

A method according to claim 34, wherein the circuit elements comprise coils having different, respective values of inductance.

Claim 36. (Original)

A method according to claim 32, wherein processing the signals further comprises determining position coordinates of the object responsive to the signals.

- Claim 37. (Original) A method according to claim 32, wherein the transducer comprises a magnetostrictive element, which is shaped so as to respond anisotropically to the acoustic waves.
- Claim 38. (Original) A method according to claim 37, wherein the magnetostrictive element is shaped to as to focus the electromagnetic radiation that it emits.
- Claim 39. (Canceled)
- Claim 40. (Previously Presented) A method for determining the position of an object within a body of a subject, comprising:
fixing a transducer to the object, the transducer being wireless and configured to emit acoustic waves responsive to an electromagnetic field that is incident thereon;
- Claim 41. (Original) A method according to claim 40, wherein the transducer comprises a piezoelectric crystal, which is polarized so as to respond anisotropically to the electromagnetic field.
- Claim 42. (Original) A method according to claim 41, wherein the piezoelectric crystal has multiple opposing faces, and wherein the transducer further comprises a plurality of resonant circuit elements having different, respective resonant frequencies, the circuit elements being coupled between respective pairs of the faces of the crystal so as to cause the crystal to emit the acoustic waves at the different resonant frequencies with respective amplitudes that vary responsive to the orientation angle of the transducer.
- Claim 43. (Original) A method according to claim 42, wherein the circuit elements comprise coils having different, respective values of inductance.

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Claim 44. (Original)

A method according to claim 40, wherein the transducer comprises a magnetoacoustic transducer.

Claim 45. (Original)

A method according to claim 41, wherein the transducer comprises a magnetostrictive material.

Claim 46. (Original)

A method according to claim 41, wherein the magnetoacoustic transducer is shaped so as to respond anisotropically to the electromagnetic field, so that the acoustic waves emitted thereby vary as a function of an orientation angle of the transducer relative to the at least one field generator, and wherein processing the signals comprises determining the orientation angle of the object responsive to the signals.

Claim 47. (Original)

A method according to claim 46, wherein the magnetoacoustic element is shaped to as to focus the electromagnetic radiation that it emits.

Claim 48. (Canceled)

REMARKS

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 are in the case and presented for reconsideration.

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/173,339. Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/173,197. Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/173,298. Duly executed Terminal Disclaimers are enclosed herewith. Accordingly, these rejections should be removed.

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38, and 40-47 have been have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,868,673 (Vesely) in view of U.S. Patent No. 5,353,354 (Keller et al.) and further in view of U.S. Patent No. 6,347,241 (Burbank et al.).

Applicant respectfully traverses as follows. The invention being claimed in Claims 1, 4, 8 and 16 respectively of the present application is an apparatus for determining the position of an object within a patient's body comprising at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object comprising a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave at a second frequency different from the first frequency (Claim 1) or at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object that emits a second acoustic wave at a second frequency different from the first frequency (Claim 4) or at least one acoustic generator for generating acoustic waves toward the body and a wireless transducer that emits electromagnetic radiation responsive to the acoustic wave (Claim 8) or at least one field

generator for generating an electromagnetic field within the body and a wireless transducer fixed to the object that emits acoustic waves responsive to the electromagnetic field (Claim 16); and one or more detectors to detect the second acoustic wave (Claim 1) or to detect the reflected acoustic waves (Claim 4) or to detect the emitted electromagnetic radiation (Claim 8) or to detect emitted acoustic waves (Claim 16) and to generate signals responsive thereto; and a signal processor for processing the signals to determine six-dimensional position and orientation coordinates of the object within the patient's body.

The invention being claimed in Claims 25, 28, 32 and 40 respectively of the present application is method for determining the position of an object within a patient's body comprising the steps of fixing a wireless acoustic tag to the object wherein the tag comprises a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave in response to a first acoustic wave at a first frequency wherein the second acoustic wave is at a second frequency different from the first frequency (Claim 25) or fixing a wireless acoustic tag to the object wherein the wireless tag emits acoustic waves in response to first acoustic waves at a first frequency with a first spatial pattern of intensity variation wherein the acoustic waves are emitted by the tag at a second frequency with a second special pattern of intensity variation (Claim 28) or fixing a wireless transducer to the object wherein the transducer emits electromagnetic radiation in response to acoustic waves directed toward the body (Claim 32) or fixing a transducer to the object wherein the transducer emits acoustic waves in response to a generated electromagnetic field (Claim 40); and inserting the object in the patient's body; and detecting the second acoustic wave (Claim 25) or detecting the reflected acoustic waves (Claim 28) or detecting the emitted electromagnetic radiation (Claim 32) or detecting the emitted acoustic waves (Claim 40); and to generate signals responsive thereto so as to determine six-dimensional position and orientation coordinates of the object within the patient's body.

Vesely discloses a system for carrying out surgery, biopsy and ablation of a tumor or other physical anomaly wherein its system uses transducers that are hard-wired from a tumor location in breast tissue all the way back to its computer system 1010 wherein the leads "can be taped to the patient's skin". Col. 7, lines 12-16. Vesely does not in any way teach or suggest a wireless acoustic tag fixed to the object comprising a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave at a

second frequency different from the first frequency (Claim 1) or at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object that emits a second acoustic wave at a second frequency different from the first frequency (Claim 4) or at least one acoustic generator for generating acoustic waves toward the body and a wireless transducer that emits electromagnetic radiation responsive to the acoustic wave (Claim 8) or at least one field generator for generating an electromagnetic field within the body and a wireless transducer fixed to the object that emits acoustic waves responsive to the electromagnetic field (Claim 16) in conjunction with a signal processor to determine six-dimensional position and orientation coordinates, such as six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations), such as found with Applicant's claimed present invention. Moreover, for the same reasons as outlined above, Vesely fails to teach or suggest these limitations as part of a method for determining the position of an object within a patient's body such as set forth in Applicant's Claims 25, 28, 32 and 40 of the Present Application.

Contrary to the Examiner's interpretation of the teachings of this reference, Vesely is clearly directed to a three-dimensional tracking system only and entirely incapable of determining both position and orientation coordinates (six dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations) such as found with Applicant's claimed present invention.

Particularly, in the portion of the teaching pointed out by the Examiner, i.e. Col. 4, Lines 55-65, Vesely specifically teaches:

Imaging modality system 1014 acquires 2-D, 3-D or 4-D image data sets from an imaging source, such as fluoroscopy, an MRI (magnetic resonance imaging), CT (computerized tomography) or 2-D or 3-D ultrasound device, to provide a "template" through or against which the shape, position and movement of instrument 1030 being tracked can be displayed. The template typically takes the form of an image of the environment surrounding the instrument (e.g., a bodily structure). It should be noted that if multiple (3-D) volumes are acquired at different time intervals, a 4-D image is obtained (i.e., 3-D image changing over time).

Thus, the system and method of Vesely is only capable of producing “multiple (3-D) volumes” and is required to be combined with a separate imaging modality in order to produce a 4-D image at best.

Keller et al. is directed to the acquisition and display of ultrasonic images from sequentially oriented image planes. It is important to note that these image planes are derived purely from an external ultrasonic scanhead 10 which is used on an exterior surface of the patient’s body. See FIGS. 5 and 6.

Burbank actually teaches an ultrasonic and x-ray detectable biopsy site marker and apparatus for applying it that merely uses radio opaque gelatin pellets to mark a biopsy site in tissue. These gelatin or collagen-based pellets could not in any way cause signals that are generated and received by a signal processor for determining six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations of a wireless acoustic tag/wireless transducer as found with Applicant’s claimed present invention. But rather, the Burbank et al. pellets are based strictly on hydration and are identified in the tissue of the patient’s body based on the trapped air pockets in the gelatin or collagen (that are visible on an ultrasound image) that result from hydration of the implanted pellet. See Col. 4, Line 57 – Col. 5, Line 11.

The claimed present invention does not at all use or claim Burbank et al.’s hydration-based gelatin or collagen pellet. And, Burbank et al. clearly teaches away from the wireless tag/wireless transducer six-dimensional position and orientation coordinate technology in which the Applicant is claiming. Thus, at the time of Applicant’s invention, the art actually taught away from the Applicants’ invention. Thus, Burbank et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Vesely and Keller et al. to render the present invention obvious.

Therefore, one skilled in the art would not be lead by the teachings of Keller et al. to experiment with their external ultrasonic scanhead and ultrasonic image plane display system or Burbank et al.’s hydration-based gelatin or collagen pellet. Thus, contrary to the Examiner’s assertions, Vesely is actually evidence of the non-obvious of the present invention. See *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986).

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Col. 4, Lines 55-65 of Vesely, its system can only ensure that “multiple (3D) volumes are acquired at different time intervals, a 4-D image is obtained (i.e., 3-D image changing over time)”. Accordingly, this 3-D volume technique can never achieve the determination of six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations of a wireless acoustic tag or wireless transducer such as found with Applicant’s claimed present invention. Thus, one of ordinary skill in the surgical navigation field would be entirely discouraged from following the path set out in the teachings of Vesely. And, it is clear that this reference actually teaches away from Applicant’s claimed present invention.

Therefore, for the reasons outlined above, the Applicants claimed present invention is both patentably distinct and non-obvious over the cited prior art references, and favorable action is respectfully requested.

Respectfully submitted,

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